

A Request to Correct Inventorship Pursuant to 37 C.F.R. § 1.48(b) accompanies this Amendment, and requests deletion of McCarthy and Fraser as inventors, owing to cancellation of claims for which those two inventors were initially properly named. After entry of the Request to Correct Inventorship, the remaining inventors should be John D. Sharp and Thomas M. Barnes.

II. Objection to Claims for Encompassing Non-Elected Subject Matter.

At page 3 of Paper No. 10, the Examiner has objected to claims 8, 9, 24, 30, and 44 asserting that these claims encompass non-elected subject matter. Claims 8, 9, 24, and 30 have been amended to excise the SEQ ID NO: designations that the Examiner considers to be non-elected.

Claim 44 has not been amended, as it contains only the amino acid sequences of SEQ ID NOs: 47 and 49, which the Examiner has indicated are elected. *See*, page 2 of Paper No. 10.

Accordingly, as the Examiner's objections are no longer applicable, it is respectfully requested that they be withdrawn.

III. Rejections Based Upon Alleged Lack of Utility.

At pages 3-5, the Examiner has rejected claims 8-10 and 24-46 under 35 U.S.C. § 101 and § 112, contending that such claims lack utility, and, because of this alleged lack of utility, are not enabled. Because the issues implicated by each rejection are closely related, the rejections are discussed together below.

A. Rejection Under 35 U.S.C. § 101.

The Examiner asserts that claims 8-10 and 24-46 are not supported by a credible, substantial, and specific utility or a well-established utility. The Applicants respectfully traverse this rejection.

A claimed invention meets the requirements for patentable utility if the subject matter of the claim has, at least, an asserted utility that is specific, substantial, and credible. In the Office Action, the Examiner does not mention in particular the specificity of the asserted

utility for the claimed subject matter, and the Applicants therefore assume that the Examiner does not question that the asserted utilities are specific to the claimed subject matter (i.e., to polypeptides that exhibit a TANGO 294 activity). In the ensuing paragraphs, the Applicants address the Examiner's apparent concerns regarding the credibility and substantiality of the asserted utilities.

The Examiner appears to question the credibility of the utilities asserted for the claimed polypeptides. An asserted utility does not meet the criterion of credibility only if it is considered to be wholly inconsistent with known scientific principles or it is speculative as to whether the attributes of the invention necessary to impart the utility are actually present in the invention. M.P.E.P. § 2107.

The Examiner suggests that the Applicants have based their assertion that the claimed TANGO 294 polypeptides exhibit lipase or lipase-like activity only on the fact that significant overall amino acid sequence homology exists between the claimed polypeptides and various lipases. The Examiner suggests that a skilled artisan would not consider mere overall sequence similarity to be predictive of conservation of activity. Regardless of whether this latter suggestion is true, the Applicants do not base their assertion that claimed TANGO 294 polypeptides exhibit lipase activity solely on amino acid sequence homology. Additional, non-sequence-homology-based supporting evidence is provided in the specification, and the Applicants respectfully contend that the skilled artisan would accept that TANGO 294 polypeptides exhibit lipase or lipase-like activity in view of all of the evidence provided in the specification.

For example, the specification discloses that, in addition to the significant overall amino acid sequence homology that TANGO 294 shares with other mammalian lipases, the amino acid sequence of TANGO 294 protein includes specific functional amino acid sequences and residues conserved among lipases. These sequences and residues include the lipase serine active site (residues 180-189 of SEQ ID NO: 47), the amino acid residues that form the catalytic triad of the lipase active site (residues 186, 357, and 386 of SEQ ID NO: 47), two cysteine residues conserved among lipases (residues 260 and 269 of SEQ ID NO: 47), and two conserved residues that form an oxyanion hole in lipases (residues 100 and 187 of SEQ ID NO: 47).

The Applicants have enclosed with this Amendment a phylogenetic tree that shows the relationship of TANGO 294 amino acid sequence (identified as "Fbh46692 126 1397" and indicated with an arrow) with the top BLAST hits in a public protein sequence database. All of the proteins shown in the phylogenetic tree for which activities have been established (indicated by stars) are lipases, sterol hydrolases (which catalyze deacylation of a sterol - a reaction analogous to lipase activity, which is deacylation of a lipid), or both. In view of all of these similarities between TANGO 294 and known lipases (including known rat, dog, and human lipases, as indicated on page 75, lines 17-23, of the specification), the skilled artisan would accept that TANGO 294 is a lipase, or at least exhibits lipase-like activity.

Also enclosed with this Amendment are a series of images of Northern blot analyses of fetal and adult human tissues. Significant expression of TANGO 294 (designated "46691" in the Northern blots) was detected only in stomach tissue under the experimental conditions and samples used. This expression is consistent with TANGO 294 being a lipase.

The Applicants therefore respectfully contend that they have established that TANGO 294 is a lipase. In view of the evidence presented in the specification and with this Amendment, the Applicants respectfully suggest that the Examiner has not satisfied the burden of showing that the claimed invention does not have a credible utility.

The Office's Utility Examination Guidelines indicate that the Examiner must accept the Applicants' assertion of utility as credible unless the Examiner can demonstrate either that the logic underlying the assertion is seriously flawed, or that the facts upon which the assertion is based are inconsistent with the logic underlying the assertion (M.P.E.P. § 2107, Subheading II, in the paragraph following paragraph D, copy of relevant pages enclosed). The Applicants respectfully contend that the Examiner has not demonstrated either that linkage of the evidence provided in the specification and with this Amendment with the Applicants' assertion that TANGO 294 polypeptides exhibit lipase and lipase-like activities is logically flawed or that the evidence is inconsistent with the Applicants' assertion. The Examiner has therefore not met his burden of showing that the asserted utility is not credible.

The Examiner questions whether the claimed polypeptides have a "real world" utility, suggesting that he believes that the claimed polypeptides do not have a substantial utility. The Examiner's doubt regarding the substantiality of utility of the claimed polypeptides

appears to stem from the Examiner's refusal to believe that the claimed polypeptides are indeed lipase family members which exhibit lipase or other TANGO 294 activity. All of the claims, as amended, recite that the claimed polypeptides include only those that exhibit one of the TANGO 294 activities disclosed in the specification (e.g., at page 76, line 21, through page 77, line 7). The Applicants contend that the claims include only polypeptides that exhibit a TANGO 294 activity, and that therefore have a utility that the Examiner recognizes as substantial.

The Examiner suggests that the claims include within their scope polypeptides that would not exhibit a utility asserted in the specification. The claims have been amended such that every pending claim recites that the claimed polypeptide exhibits either a lipase activity, or another TANGO 294 activity. The Applicants respectfully contend that these amendments remove inactive embodiments from the scope of the claims, and that the Examiner's concern in this regard is no longer warranted.

For the foregoing reasons, it is requested that the Examiner reconsider and withdraw the 35 U.S.C. § 101 rejection.

B. Rejection Under 35 U.S.C. § 112, first paragraph, Utility/Enablement.

At page 5 of Paper No. 10, the Examiner rejects claims 8-10 and 24-36 under 35 U.S.C. § 112, first paragraph, asserting that, because the claimed polypeptides do not have a utility under 35 U.S.C. § 101, they are not enabled because one skilled in the art would not be able to use them. The Applicants traverse this rejection.

The analyses of whether a claim lacks utility are identical, regardless of whether such rejection is grounded in § 101 or § 112, M.P.E.P. § 2107(iv). The how-to-use prong of § 112 incorporates, as a matter of law, the requirement of § 101, that the specification discloses as a matter of fact a practical utility for the invention. M.P.E.P. § 2107(iv), citing *In re Ziegler*, 992 F.2d 1197, 1200-1201 (Fed. Cir. 1993).

For reasons presented above in part A of this response, the Examiner has failed to satisfy the factual showing necessary to support a § 101 rejection, because the claimed invention has, at least, an asserted utility that is substantial, specific, and credible. Therefore, the § 112-based utility/enablement rejection cannot stand as a matter of law. Accordingly, it is

respectfully submitted that the Examiner should reconsider and withdraw the § 112, first paragraph, rejection for lack of utility.

IV. Rejection Under 35 U.S.C. § 112, first paragraph - Enablement.

At pages 5-7, the Examiner has rejected claims 8, 10, 24-39, and 42-46, asserting that portions of such claims are not enabled by specification. In particular, the Examiner has argued that those portions of the rejected claims which encompass fragments of SEQ ID NO: 47, "% variants of the fragments," allelic variants of SEQ ID NO: 47, hybridization variants, and "% variants," are not enabled by the specification.

Claims 8 and 30 have been amended without prejudice to excise those portions of the claim reciting "allelic variants of SEQ ID NO: 47." Accordingly, the Examiner's rejection with respect to this specific language is no longer applicable. Each of the claims, as amended, recites (or depends from a claim that recites) that the polypeptide exhibits a TANGO 294 activity. With respect to the remaining grounds of the rejection, the Applicants respectfully traverse.

The test of enablement is whether the disclosure, when filed, contains sufficient information regarding the subject matter of the claims so as to enable one skilled in the art to make and use the claimed invention. Enablement turns on a determination of whether one reasonably skilled in the art could make and use the invention from the disclosures in the patent, coupled with information known in the art, without undue experimentation. M.P.E.P. § 2164.01, citing *In re Wands*, 858 F.2d 731-737 (Fed. Cir. 1998). However, it is well settled that an application need not teach, and preferably omits, that which is known in the art. M.P.E.P. § 2164.01.

Evaluated under this analysis, the full scope of claims 8, 42, 46, 10, 24-39, and 43-45, with respect to fragments of SEQ ID NO:47, % variants of fragments of contiguous amino acid residues of SEQ ID NO: 47, hybridization variants of SEQ ID NOs: 45 and 46, and of the clone deposited as ATCC™ 207220, is enabled.

Means of making and using the isolated polypeptides of the invention, including fragments, hybridization variants, and % identity variants, are found in the specification at least

at pages 77, line 10 to page 78, line 6 (methods by which variant nucleic acids encoding functional TANGO 294 proteins and fragments can be made).

Further, it is identified in both the specification and the claims that the polypeptides of the invention, including fragments, % variants, and hybridization variants, contain specific primary sequences, identified by SEQ ID NO: designation, exhibit lipase activity, and/or hybridize to the primary sequences under specific hybridization conditions, which are recited in the claims. The means by which fragments of proteins (and nucleic acid molecules that encode such fragments) can be made were well known in the art, and methods and protocols for the screening of such fragments for biological activities (e.g., lipase activity) were routine at the time this application was filed.

The claims have been amended so that they encompass only polypeptides that exhibit a TANGO 294 activity (e.g., a lipase or lipase-like activity). The relevant property of the claimed polypeptides for most uses is their activity. Numerous lipase activity assays are known in the art (see, e.g., the enclosed abstracts by Duque et al., Hendrickson, and Bariszlovich et al.), as are assays for assessing the other lipase-like activities recited in the claims. The skilled artisan would have no difficulty performing one of these routine assays in order to determine whether a selected polypeptide exhibits the relevant activity. For the foregoing reasons, the Applicants respectfully contend that the skilled artisan is able to make all of the polypeptides encompassed by the pending claims.

The skilled artisan is also able to use the claimed polypeptides regardless of which particular polypeptide is selected, so long as the polypeptide has the characteristics recited in the claims. The Examiner has not suggested or shown otherwise. The specification explicitly envisions use of TANGO 294 polypeptides in which conservative amino acid substitutions have occurred or been made (see page 95, line 16, through page 96, line 5, and page 88, line 26, through page 89, line 26). The Applicants respectfully contend that the specification enables the skilled artisan to use the polypeptides recited in the claims.

Thus, a skilled artisan, using the information provided in the specification coupled with the information and techniques available and known in the art, would be able to make and use the claimed polypeptides and to readily ascertain which polypeptides are within the scope of each of the pending claims. Accordingly, the full scope of each of the claims is

fully enabled by the specification, and the Applicants respectfully request that the Examiner reconsider and withdraw his rejection of claims 8, 10, 24-39, and 42-46 for lack of enablement.

V. Rejection Under 35 U.S.C. § 112, first paragraph - Written Description.

On page 7 of the Office Action, the Examiner contends that the specification does not include an adequate written description of the allelic variants of SEQ ID NO: 47, as recited in claims 8 and 30. Allelic variants are no longer recited in the claims, and the Examiner's written description rejection is believed to be moot. The Applicants respectfully contend that the level of detail presented in the specification regarding the important regions and residues of SEQ ID NO: 47 provide the skilled artisan with sufficient guidance that, in view of what was known in the art at the time the application was filed, the skilled artisan can envision the polypeptides recited in the claims.

For the foregoing reasons, the Applicants request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 112, first paragraph, for failure to comply with the written description requirement.

VI. Rejection Under 35 U.S.C. § 112, Second Paragraph.

At pages 7-8 of Paper No. 10, the Examiner has rejected claims 8-10, and 24-45 under 35 U.S.C. § 112, second paragraph, asserting that such claims are indefinite for failing to particularly point out and distinctly claim the subject matter which the Applicants regard as the invention. Each of the specific rejections is addressed in the order it appears in the Office Action.

At the pages 7 and 8 of the Office Action, the Examiner has rejected claims 8 and 30, asserting that these claims are incomplete because they omit essential elements; specifically, that the specification lacks a specific definition of hybridization conditions. While not necessarily agreeing with the Examiner, the Applicants have amended claims 8 and 30 to recite specific hybridization conditions disclosed in the specification at page 87, lines 21-24. Therefore, the Examiner's rejection of claims 8 and 30 as being indefinite is no longer applicable.

At the second full paragraph of page 8, the Examiner has rejected claim 31, asserting that it is incomplete for omitting essential elements. Claim 31 has been cancelled; therefore the Examiner's rejection is no longer applicable. However, because the stringency conditions of claim 31 have been added to claims 8 and 30, the Applicants will address the rejection here. The Examiner contends that the recitation of stringent hybridization conditions must recite the duration of the washing portion of the conditions. The Applicants respectfully contend that duration of washing is dependent on the precise apparatus and arrangement used for hybridization and washing, but that these factors are well known for any particular apparatus and arrangement (see, for example, the enclosed portion of Unit 2.9 of "Short Protocols in Molecular Biology, 2nd Ed.," especially at the lines marked on pages 2-25, 2-26, 2-27 and 2-28). The skilled artisan would have no difficulty selecting an appropriate duration for the washing step in view of the apparatus and arrangement used by the artisan. Selection of such factors is routine in nucleic acid hybridizations. The Applicants request that the Examiner reconsider and withdraw this rejection.

Also at page 8, the Examiner has rejected claim 8, asserting that it is further indefinite for the recitation of "either of SEQ ID NO: 47 and amino acid sequence" in part a), lines 3-4. The Applicants have amended claim 8 as suggested by the Examiner by substituting "or" for "and."

Also at page 8, the Examiner has rejected claims 8, 42, and 43 as indefinite for recitation of "a portion which . . .". Claim 8 has been amended to clarify that the polypeptide exhibits a TANGO 294 (e.g., lipase) activity, the recitation applying to all parts of the claim, including part c). The Applicants submit that the Examiner's rejection is no longer applicable. Accordingly, its withdrawal is requested.

The Examiner has also rejected claims 8, 9, 24, and 30 for recitation of "any of SEQ ID NOs: 47-52 and the amino acid sequence . . .". The Applicants have amended these claims as suggested by the Examiner. Therefore, the Examiner's rejection is believed to be no longer applicable.

The Examiner has rejected claims 9 and 35, asserting that they are indefinite for the recitation of "a complement thereof." The Applicants have amended claims 9 and 35 to

exclude the language "a complement thereof." As the Examiner recognizes, the deletion of this term does not alter the scope of the claim, but merely clarifies the claim language.

The Examiner has rejected other claims as depending from one or more of the claims rejected under 35 U.S.C. § 112, second paragraph. Because the Applicants believe that all of the rejections under 35 U.S.C. § 112, second paragraph, either have been overcome or should be withdrawn, the Applicants respectfully contend that no claim depends from a claim that is properly rejected under 35 U.S.C. § 112, second paragraph.

In view of the foregoing, it is respectfully requested that the Examiner reconsider and withdraw his rejection of claims 8-10 and 24-45 under 35 U.S.C. § 112, second paragraph.

SUMMARY

In view of the foregoing, it is respectfully submitted that claims 8-10, 24-26, 28-30, 33-36, and 38-47 are fully compliant with 35 U.S.C. §§ 112 and 101 and all other relevant statutes and rules. Accordingly, reconsideration and allowance of the claims at the earliest opportunity are earnestly solicited.

Respectfully submitted,

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(Date)

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Enclosures: Petition for Extension of Time
Marked Up Version of Claims as Amended
Clean Copy of Pending Claims
Declaration and Power of Attorney (executed)
Request to Correct Inventorship
Phylogenetic Tree
Four Northern Blots of TANGO 294 ("46691") Expression, on 2 pages
Copy of excerpt of MPEP §2107, Subheading II
Abstracts by Duque et al., Hendrickson, and Bariszlovich et al.
Portion of Unit 2.9 of "Short Protocols in Molecular Biology," 2nd Ed. (1992)